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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/397,550	09/16/1999	JASON PETER BROWN	A0000180-66-	8892

7590 01/27/2003

WARNER-LAMBERT COMPANY
2800 PLYMOUTH ROAD
ANN ARBOR, MI 48105

EXAMINER
MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
1646	16

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/397,550	BROWN ET AL.	
	Examin r	Art Unit	
	Joseph F Murphy	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/1/2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4 and 10-25* is/are pending in the application.

4a) Of the above claim(s) *13-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4, 10-12, 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/8/2002 has been entered.

Formal Matters

Claims 2-4, 10-11, 23 were amended, and new claims 24-25 were added, in Paper No.15, 11/1/2002. Claims 2-4, 10-25 are pending. Claims 13-22 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 2-4, 10-12, 23-25 are under consideration.

Specification

The disclosure is objected to because of the following informalities: According to 37 CFR 1.821(d) (MPEP § 2422), where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. Sequences appear, *inter alia*, on page 20, lines 14-20, of the specification but are not identified by "SEQ ID NO" as required. The use of "SEQ ID N°" is not in compliance with the requirements of 37 CFR 1.821(d).

Appropriate correction is required.

Claim Objections

Claims 2-4, 23, 24 are objected to because of the following informalities: According to 37 CFR 1.821(d) (MPEP § 2422), where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. The use of "SEQ ID N°" is not in compliance with the requirements of 37 CFR 1.821(d).

Appropriate correction is required.

Response to Amendment

The rejection of claims 2 and 3 under 35 USC § 112 second paragraph has been obviated by Applicant's amendment, and is thus withdrawn.

The rejection of claims 1 and 12 under 35 USC § 112 first paragraph has been rendered moot by cancellation of claim 1, and obviated by the amendment of claim 12, and is thus withdrawn.

The rejection of claims 1 and 12 under 35 USC § 112 second paragraph has been rendered moot by cancellation of claim 1, and obviated by the amendment of claim 12, and is thus withdrawn.

The rejection of claims 10-12, 23 under 35 U.S.C. 102(b) as being anticipated by WO 9504822 (Harpold et al.) has been obviated by Applicant's amendment, and is thus withdrawn.

Claim Rejections - 35 USC § 112first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-3, 10-12, 23-25 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding a substantially purified polypeptide comprising an amino acid sequence set forth in SEQ ID NO: 20 and 22, or a polynucleotide encoding a fragment from amino acid 1 to amino acid 1062 of SEQ ID NO: 20, or a polynucleotide encoding a fragment from amino acid 1 to amino acid 1019 of SEQ ID NO: 22, which binds gabapentin, does not reasonably provide enablement for a polynucleotide having 90% identity to a nucleic acid encoding a substantially purified polypeptide comprising an amino acid sequence set forth in SEQ ID NO: 20 and 22, or a polynucleotide having 90% identity to a nucleic acid encoding a fragment from amino acid 1 to amino acid 1062 of SEQ ID NO: 20, or a polynucleotide having 90% identity to a nucleic acid encoding a fragment from amino acid 1 to amino acid 1019 of SEQ ID NO: 22. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are overly broad in the recitation of "at least 90% identical" since insufficient guidance is provided as to which of the myriad of polynucleotide species encoding polypeptide species encompassed by the claim will retain the characteristics of a voltage-dependent calcium channel. The specification provides insufficient guidance how to generate voltage-dependent calcium channels, and does not disclosing any actual or prophetic examples on expected

performance parameters of any of the possible muteins of voltage-dependent calcium channels. It is known in the art that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function. It is also known in the art that a single amino acid change in a protein's sequence can drastically affect the structure of the protein and the architecture of an entire cell. For example, Voet et al. (1990) teaches that a single Glu to Val substitution in the beta subunit of hemoglobin causes the hemoglobin molecules to associate with one another in such a manner that, in homozygous individuals, erythrocytes are altered from their normal discoid shape and assume the sickle shape characteristic of sickle-cell anemia, causing hemolytic anemia and blood flow blockages (pages 126-128, section 6-3A and page 230, column 2, first paragraph).

Since the claims encompass variant nucleic acids and given the art recognized unpredictability of the effect of mutations on protein function, it would require undue experimentation to make and use the claimed invention. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors considered to be relevant in the instant case are set forth below:

(1) the breadth of the claims - The instant claims are drawn to a polynucleotide having 90% identity to a nucleic acid encoding a substantially purified polypeptide comprising an amino acid sequence set forth in SEQ ID NO: 20 and 22, or a polynucleotide having 90% identity to a nucleic acid encoding a fragment from amino acid 1 to amino acid 1062 of SEQ ID NO: 20, or a polynucleotide having 90% identity to a nucleic acid encoding a fragment from amino acid 1 to amino acid 1019 of SEQ ID NO: 22.

(2) the nature of the invention - The instant invention is a polynucleotide having 90% identity to a nucleic acid encoding a substantially purified polypeptide comprising an amino acid sequence set forth in SEQ ID NO: 20 and 22, or a polynucleotide having 90% identity to a nucleic acid encoding a fragment from amino acid 1 to amino acid 1062 of SEQ ID NO: 20, or a polynucleotide having 90% identity to a nucleic acid encoding a fragment from amino acid 1 to amino acid 1019 of SEQ ID NO: 22.

(3) the state of the prior art - The Voet reference demonstrate that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function.

(5) the level of predictability in the art - The Voet reference demonstrate the unpredictability of the protein art.

(6) the amount of direction provided by the inventor - Applicant has only taught three nucleic acids encoding polypeptides which bind gabapentin.

(7) the existence of working examples - Working examples are provided only for three nucleic acids encoding polypeptides which bind gabapentin.

(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure - Based on the content of the disclosure and the breadth of claims 2-3, 10-12, 23-25 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use a polynucleotide having 90% identity to a nucleic acid encoding a substantially purified polypeptide comprising an amino acid sequence set forth in SEQ ID NO:

20 and 22, or a polynucleotide having 90% identity to a nucleic acid encoding a fragment from amino acid 1 to amino acid 1062 of SEQ ID NO: 20, or a polynucleotide having 90% identity to a nucleic acid encoding a fragment from amino acid 1 to amino acid 1019 of SEQ ID NO: 22.

Claims 2-3, 10-12, 23-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The claims encompass a polynucleotide having 90% identity to a nucleic acid encoding a substantially purified polypeptide comprising an amino acid sequence set forth in SEQ ID NO: 20 and 22, or a polynucleotide having 90% identity to a nucleic acid encoding a fragment from amino acid 1 to amino acid 1062 of SEQ ID NO: 20, or a polynucleotide having 90% identity to a nucleic acid encoding a fragment from amino acid 1 to amino acid 1019 of SEQ ID NO: 22. These are genus claims. The scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claim do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not

supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a nucleic acid encoding SEQ ID NO: 20 and 22 is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4 and 23 are rejected, under 35 U.S.C. 102(b) as being anticipated by Wei et al. (1998).

Wei et al. discloses a human alpha 2 calcium channel which is 100% identical to SEQ ID NO: 1 (See Sequence Comparison A, attached to Paper No. 8, 3/7/2001). This mRNA was cloned into a vector and expressed in host cells, thus anticipating claims 4 and 23.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
January 24, 2003